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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/242,254	05/07/99	FORSSMANN	W FORSSMANNETA

COLLARD & ROE  
1077 NORTHERN BOULEVARD  
ROSLYN NY 11576

HM12/0912

EXAMINER

BASKAR, P

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
**09/242,254**

Applicant(s)  
**FORSSMANN ET AL**

Examiner  
**Padma Baskar**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on Aug 2, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-13 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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***Response to Amendment***

1. The amendment filed on 8/2/00 has been entered into the record.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Rejections Maintained***

3. Rejection of claims 1-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are maintained for essentially the same reasons as the rejections of claims 1-13 under this statutory provision, as set forth in the last Office action.

Claim 1 is rejected as being vague and indefinite for the recitation of "condition". It is not clear to the examiner what are the meets and bounds of "condition"? What does applicant intend this to mean?

Claim 1 is rejected as being vague and indefinite for the recitation of "hypotheses". It is not clear to the examiner what the applicant wants to point out. This is a method of detection and it is not based on any hypothesis. What does "without the need to recur to hypothesis" mean?

Claim 1 is rejected as being vague and indefinite for the recitation of "reference". It is not clear to the examiner what are the meets and bounds of "reference"? Is this a positive control or a negative control? Does applicant want to compare the results to a known standard reference? If so, what is the standard?

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Claim 4 is rejected as being vague and indefinite for the recitation of " corresponds to that of dipeptide". It is not clear to the examiner how the measurement of low molecular weight peptides corresponds to that of dipeptide? What are these dipeptide? How is the molecular weight determined, what is the method?

Claim 8 is confusing. What is the method to characterize low molecular weight peptides?

Claim 11 is rejected as being vague and indefinite for the recitation of " derived". In order to derive a sample from genetically engineered or transformed and/or conditioned organisms there are several steps to obtain such sample. What are those steps?

Claim 11 is rejected as being vague and indefinite for the recitation of "and/or." It is not clear whether the invention is the combination or the individual components used by themselves

Claim 12 and 13 are rejected as being vague and indefinite for the recitation of "hypotheses". It is not clear to the examiner what the applicant wants to point out. This is a method of detection and it is not based on any hypothesis.

Claim 12 is totally confusing. How is the overall condition of an individual determined by this method? Is a sample taken periodically? What is the reference condition mean?

Claim 13 is rejected as being vague and indefinite for the recitation of "causally." How is this defined?

Applicants' arguments filed on 8/2/00 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the present invention is a general method for identifying the condition of organism, First of all it is totally confusing with respect to what applicant means by organism? Is it an individual ? Is it a bacteria? Is it a virus? Is it a parasite? Since this not clear to the examiner then the arguments about the terms "without the need to recur to hypotheses"

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"condition" and "references" are not understood. Further examiner is confused of the term "condition." Does this mean good condition or bad condition? Is it a chronic stage of the infection? Is it a acute stage of the infection? Is it a relapse or what?

Finally applicant argues about dipeptide and indicates that they are gly-gly. Applicant is arguing about the limitations which are not set forth in the claims.

Applicant further argues about the term "derived." If the sample is derived from genetically engineered or transformed and/or conditioned organisms then how is the condition of an organism determined by this method? And also how is the sample obtained? Applicant is advised to amend the claim 1 clearly to recite the claimed invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete because it omits essential steps, such omission amounting to a gap between the steps. See MEP\$2172.01. The omitted steps are:

1. What is contacted with this method?
2. What is detected?
3. What is correlated?

Method claims need not recite all operating details but should be at least recite positive, active steps so that the claim will set out and circumscribe particular areas with a reasonable degree of precision and particularity and make clear what subject matter claims encompass, as well as make clear subject matter from which others would be precluded.

4. Rejection of claims 1-4, 8, 10, 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Harry et al, 1989 (Clinical Microbiology Reviews, Vol 2, pages 241-249) is maintained for

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essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides.

Harry et al disclose a method for detecting HIV p24 antigen by using commercially available capture assays from a sample (see page 241 and Table 1). The prior art anticipates the claimed invention.

Applicants' arguments filed on 8/2/00 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the method disclosed by Harry et al directed to protein or fragments and is relevant for the condition of the **organism I (NOT organism: it should be individual)** whereas the claimed invention is for the analysis of low molecular weight peptides. Examiner disagrees with the applicant because Harry et al's method also detects the low molecular weight peptides such as p24 and depending on the amount of the p24 antigen, stage of infection could be diagnosed. Since the claimed invention is not clearly recited by the claims and are so broadly written, the prior art anticipates the claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., peptide function; direct measurement; relevance to individual's condition ) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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5. Rejection of claims 1-4, 8, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ausubel et al 1995 (Short Protocols In Molecular Biology, Chapter on analysis of proteins ) is maintained for essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides.

Ausbel et al disclose a number of methods for protein analysis in Chapter 10. For example Immunoaffinity Chromatography, Reversed-Phase High-Performance Liquid Chromatography. All these methods are used to detect high and low molecular weight peptides in a sample, (see pages 10-54-10-58; 10-64-10-69). The prior art anticipates the claimed invention.

Applicants' arguments filed on 8/2/00 have been fully considered but they are not deemed to be persuasive.

Applicant argues that Ausubel does not disclose any method which detects low molecular weight peptides. Examiner disagrees and again emphasizes that the independent claim 1 is so poorly written and also very broad any method such as the method described by Ausubel would read on the claims. Since the term "condition" is not clear, the prior art anticipates the claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., condition/status of an individual, references from other organisms; characterization of low molecular weight or dipeptides) are not recited in the rejected claim(s). Although the claims are

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interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Rejection of claims 1-13 under 35 U.S.C. 102(b) as being anticipated by Jimenez et al 1994 (Journal of Neurochemistry; Vol 62; pages 404-407) is maintained for essentially the same reasons as the rejections of claims 1- 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides by mass spectrometry.

Jimenez et al disclose a method, matrix-assisted laser desorption ionization mass spectrometry (MALDI-MS) technique for identifying neuronal peptides with low molecular weights from snails (see experimental procedures and figure 2 and 3). The prior art anticipates the claimed invention.

Applicants' arguments filed on 8/2/00 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the Jimenez et al does not disclose the claimed invention rather discloses a method which identifies high molecular weight substances. Further he argues that Jimenez et al's method does not disclose the condition of organism. Since the term condition is not clear and the claims are broad this prior art applies as it detects low molecular weight peptides.

#### ***Status of Claims***

7. No claims are allowed.



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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

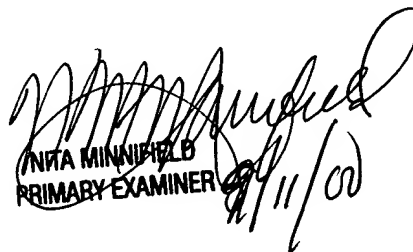
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/8/00

  
INPA MINNIEFIELD  
PRIMARY EXAMINER  
9/11/00